Purpose

The purpose of this Guide is to present a pro-active approach to identify service improvement opportunities.

Scope

This Guide applies to any technical or quality systems that relate to the calibration/testing services of the Ionizing Radiation Division.

Definitions

Equipment

N/A

Health & Safety Precautions

N/A

Protocol

Opportunities for needed improvement and potential sources of nonconformance may be identified in several ways. These include, but are not limited to, observations in other laboratories, suggestions made by visiting scientists, ideas based on the experience of NIST personnel, and necessary upgrades of equipment or computer programs.

Initiation of preventive action

The initiator of the preventive action should discuss the action plan thoroughly with his/her Group Leader and other staff members, when appropriate, to determine feasibility of the plan.

When it is decided to put the plan into action, a Preventive Action Form will be filled out and signed by the preparer and the Group Leader (Appendix IRD-G-09.A). The Preventive Action Form will then be delivered to the Quality Manager who shall sign acknowledging receipt. The Quality Manager will place the original in the Preventive Action folder and return a copy of the signed document to the preparer and Group Leader.

Implementation

When the Preventive Action Form is completed, the preparer will devise an implementation program. This will include testing before and after the installation of the action to ensure consistency. The program need not be written down formally, but all

results from the program shall be documented. The implementers of the program shall decide what constitutes acceptance.

Monitoring Results

Once the implementation is accepted, the results of the preventive action shall be monitored for a length of time appropriate to the action to ensure that the action is indeed an improvement to the overall system. The Group Leader (or someone he/she delegates) shall decide how long the monitoring shall take place. There is no formal documentation of the monitoring unless actual test results are produced, but notes in the logbook are recommended for tracking purposes.

Acceptance Criteria

The action plan is accepted when it passes all implementation tests and proves to be consistent through routine monitoring for a designated time. Once the action plan has been implemented into full service, the preparer of the plan will enter the date on the original Preventive Action Form.

If the action plan is rejected, for whatever reason, a separate sheet(s) shall be prepared indicating the implementation and/or monitoring test results and the reason for rejecting the plan. This will be attached to the original Preventive Action Form.

If the action plan is modified, no further indications need to be made on the Preventive Action Form unless a complete change of action is indicated. In that instance, a new Preventive Action Form will be prepared and the first rejected as above.

References

N/A

Documentation

Preventive Action Form
Logbooks

Filing and Retention

The original Preventive Action Form will be placed in the Preventive Action folder. Logbooks are kept in the calibration laboratories.

Appendix IRD-G-09.A

PREVENTIVE ACTION FORM

REASON FOR PREVENTIVE ACTION

_____

_____

_____

_____

_____

PREVENTIVE ACTION TAKEN

___ New protocol

___ Revised protocol

___ Modify equipment (explain below or on separate sheet of paper)

___ Addition or replacement of equipment

Equipment _____

Vendor _____

___ Other (explain below or on separate sheet of paper)

_____

_____

_____

Preparer _____ Date _____

Group Leader _____ Date _____

Quality Manager _____ Date _____

Date preventive action implemented into full service _____